IV. REMARKS ON THE AMENDMENT TO THE CLAIMS

The amendment contained with this submission merely cancels claims that have been withdrawn from consideration by the Examiner due to the issuance of a restriction requirement. Accordingly, it is believed that entry of this amendment is proper since it merely puts that application in condition for allowance or appeal.

V. REMARKS ON EXAMINER'S OBJECTION

At paragraph 2 of the present Office Action the Examiner maintained an objection to the specification, arguing that Applicants improperly attempted to incorporate by reference. In response to this same rejection that appeared in the prior Office Action (action dated July 27, 2004), Applicants noted that the Examiner did not request any corrective action and therefore no amendments appear to be needed to place the specification in condition for allowance. The Examiner did not challenge this assertion by Applicants in the present Office Action. Accordingly, it is still expected that no correction to the specification is needed to overcome the Examiner's continued objection.

Regardless, the Examiner appears to be suggesting that the information asserted to be incorporated by reference in the specification is necessary to meet the enablement and/or written description requirements of 35 U.S.C. § 112, first paragraph (c.f. the Examiner's rejections and comments in paragraphs 4-13 of the present Office Action). Applicants not only disagree with this assertion, but further note that the Examiner's reliance on "*Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2004) 54 USPQ2d at 1679 is misplaced as this decision fails to address the issue at hand.

The decision in *Advanced Display Systems Inc.*, and the precedent cited therein upon which the Examiner relies in making his objection, pertains to the making of a determination of whether or not a prior art reference anticipates the claimed subject matter of a later filed patent application depending upon whether or not certain information has been properly incorporated by reference. In these cases, if the information was properly incorporated by reference in the earlier filed patent then anticipation exists under 35 U.S.C. § 102 with respect to the later filed patent application. If not, then the legal analysis would turn on an obviousness determination under 35 U.S.C. § 103(a). Since the Examiner's objection to the specification appears to be related to his later articulated rejections under 35 U.S.C. § 112, first paragraph, it is clear that the Examiner's reliance on *Advanced Display Systems Inc.* is misplaced and hence erroneous.

Moreover, surely the Examiner is aware that: "*To satisfy the written description requirement a patent specification must describe the claimed invention in sufficient detail that*

one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention" (emphasis added) M.P.E.P. § 2163(I). *"Information which is well known in the art need not be described in detail in the specification"* M.P.E.P. § 2163(II)(A)(2).

Accordingly, the determination of written description and enablement is viewed in light of the knowledge attributable to the ordinary practitioner. Thus, it is not necessary to incorporate by reference text from a printed patent or publication to thereby comply with the written description or enablement requirements of 35 U.S.C. § 112, first paragraph because this knowledge is imputed to the ordinary practitioner for the purposes of making the written description and/or enablement determinations. This is yet further evidence that the Examiner's objection to the specification, to the extent that he believes it supports his rejections under 35 U.S.C. §112, first paragraph, is erroneous.

VI. RESPONSE TO THE OFFICE ACTION REJECTIONS

1. Rejection under 35 U.S.C. § 112, written description requirement

(a) The Law

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." M.P.E.P. § 2163 (I)(A). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description". M.P.E.P. § 2163.04 In rejecting a claim, the examiner must set forth express findings of fact which support the lack of written description conclusion..." M.P.E.P. § 2163.04(I).

"The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed...." M.P.E.P. § 2163(II)(A)(2) "Information which is well known in the art need not be described in detail in the specification." *Id.*

"To satisfy the written description requirement a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention."

M.P.E.P. § 2163(I) An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Id.*

(b) Analysis of The Examiner's Arguments In View Of The Law

(i) The Examiner's Findings of Fact are Deficient

As stated above, the there is strong presumption that an adequate written description of the claimed invention is present when the application is filed. Therefore the examiner bears a heavy burden in setting forth express findings of fact that support a determination that the specification lacks a proper written description.

After; 1) citing to *"University of Rochester v G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428" at paragraph 4 of the Office Action; 2) reproducing several independent claims at paragraph 5 of the Office Action; and 3) providing an interpretation of the claims at paragraph 6 of the Office Action, the Examiner concludes that: *"A review of the specification fails to find adequate written description of any molecular probe and binding partner that are to be used in the claimed invention."* (OA at page 8) This asserted finding of fact is not correct.

The term "molecular probe" is defined in the specification at page 7 as:

> *"...a nucleic acid or non-nucleic acid polymer (e.g. a DNA, RNA, PNA, nucleic acid analogs, nucleic acid mimics, chimera or linked polymer) having a probing nucleobase sequence that is designed to sequence specifically hybridize to a target sequence of a target molecule of an organism of interest."*

The term "binding partner" is also defined in the specification at page 10 as:

> *"...those molecules that bind to one or more other molecules in a specific manner. Because the binding partner interactions are specific, there is a degree of selectivity that is achieved depending on the nature of the binding partners chosen. Non-limiting examples of binding partner complexes (formed from the component binding partners) include antibody/antigen interactions, nucleic acid/nucleic acid interactions, enzyme/substrate interactions and receptor/ligand interactions. A non-limiting list of ligands includes avidin (and its analogs such as Streptavidin and Lumavidin™), lectins, carbohydrates, peptides and proteins. The preferred pair of binding partners used in the practice of this invention is the antibody/antigen."*

The terms "nucleic acid", "non-nucleic acid", "target sequence", "antibody", and "peptide nucleic acid" are also defined in the definitions section of the specification (pages 7-10). The terms "binding partner" and "molecular probe", being exemplified by well-known and understood compositions, provide the ordinary practitioner with sufficient information to understand that Applicant possesses and has adequately described the present invention. The Examiner is reminded that what is well known in the art need not be recited in detail in the specification. M.P.E.P. § 2163(II)(A)(2) Moreover, since the facts upon which this rejection relies are incorrect, there is no basis for the rejection. The rejection being deficient for want of support, it should be withdrawn.

In response to Applicants' filing of January 6, 2005, the Examiner simply stated:

> *"At pages 3-9 of the response to the Office action mailed 27 July 2004 applicant's representative **offers opinion** as to what is well known in the art, to what degree a skilled artisan would interpret the description provided, as well as **opinion statements** as to what is within the level of skill of the ordinary artisan." (emphasis added, Office Action at page 11)*

followed by a quotation from MPEP § 2145. It is respectfully submitted that such a terse response is both inaccurate and incomplete.

As quoted above, in support of his rejection, the Examiner asserted (as a fact) that he could NOT find within the four corners of the specification: *"an adequate description of any molecular probe and binding partner"*. In response, Applicants directed the Examiner's attention to specific definitions of these claim elements within the specification. It is wholly inaccurate to characterize definitions in the specification as being the opinion of "applicant's representative"[1]. Furthermore, the Examiner offered absolutely no explanation as to why these definitions and the other content of the specification that supports these definitions (such as the definitions of "nucleic acid", "non-nucleic acid", "target sequence", "antibody", and "peptide nucleic acid") as well as the Examples section of the specification are deficient for the purpose of satisfying the written description requirement under 35 U.S.C. § 112, first paragraph. Accordingly,

the Examiner's response is incomplete since the burden rests with him to forth express findings of fact which support the lack of written description conclusion..." M.P.E.P. § 2163.04(I).

To characterize what a reference teaches as being the opinion of "applicant's representative" is also inaccurate. What a reference teaches is a **matter of fact.** *In re Bell*, 991 F.2d 781, 784, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993).

Applicants maintain that the 14 US patents cited at page 8 demonstrate that the ordinary practitioner knew much about what structure constitutes a PNA. Similarly, the reference to these very same patents at page 11, under the heading: "PNA Synthesis", illustrates that much was understood by the ordinary practitioner about the synthesis of PNA. Likewise, the reference to 29 different US patents at page 11 of the specification demonstrates that much was understood by the ordinary practitioner with respect to nucleic acid synthesis. The same can be said of the documents cited at pages 13 and 17. Regarding USSN 09/197,162 to which reference was made at page 14, the content of this application was published as WO99/21881 on May 6, 1999 making specific priority reference to USSN 09/197,162. Consequently, this information was also public and therefore imputed knowledge of the "ordinary practitioner" at the time of the invention.

The Examiner's failure to engage in any discussion whatsoever of how these references impact the knowledge of the ordinary practitioner is simply improper. The Examiner simply cannot establish any "facts" necessary to support a conclusion of a lack of written description unless he establishes the level of skill attributable to said ordinary practitioner in view of the references discussed above (which are cited in the specification) and then explains, by proper legal analysis, why the specification is still deficient. M.P.E.P. § 2163(II)(A)(2) Since the Examiner has made no such showing, the rejection is *prima facia* deficient. Since it is deficient, the rejection should be withdrawn.

(ii) **The Examiner's Assertions re Obviousness are Misleading, Incomplete and Erroneous**

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[1] It is noted that "applicant's representative", attorney Gildea, is also a listed inventor of the claimed subject matter.

A paragraph 8 of the present Office Action the Examiner quotes from the decision in "*University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 41 USPQ2d at 1405" (OA at page 8). Before quoting a short bit of the text from the *University of California* opinion, the Examiner concludes that obviousness cannot be relied upon for satisfaction of the written description requirement. Importantly, the Examiner provides no analysis whatsoever of how Applicants have supposedly attempted to rely upon obviousness for compliance with the written description requirement. Moreover, it is respectfully submitted that the arguments are misleading.

The full text of the paragraph quoted by the Examiner reads:

> *"As indicated, Example 6 provides the amino acid sequence of the human insulin A and B chains, but that disclosure also fails to describe the cDNA.* ***Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.*** *Lockwood, 107 F.3d at 1572, 41 U.S.P.Q.2D (BNA) at 1966. We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein. See, e.g., In re Deuel, 51 F.3d 1552, 1558, 34 U.S.P.Q.2D (BNA) 1210, 1215 (1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); In re Bell, 991 F.2d 781, 785, 26 U.S.P.Q.2D (BNA) 1529, 1532 (Fed. Cir. 1993). Thus, a fortiori, a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112, P 1. Because the '525 specification provides only a general method of producing [**22] human insulin cDNA and a description of the human insulin A and B chain amino acid sequences that cDNA encodes, it does not provide a written description of human insulin cDNA. Accordingly, the district court did not err in concluding that claim 5 is invalid for failure to provide an adequate written description." (Examiner quoted text in bold)*

In *University of California*, the patents at issue related to recombinant DNA technology and specifically to plasmids and microorganisms that produce human insulin. Although the specification provided a written description of rat cDNA, it did not provide an adequate written description of human cDNA. Because of the

redundancy of the genetic code, the information provided in the specification did not allow the ordinary practitioner to surmise the, then unknown, structure of human cDNA, needed to produce the human insulin. Thus, the court concluded that a specification that only describes rat cDNA did not provide an adequate written description of human cDNA.

In the present case the Examiner has tersely concluded that: "*A review of the specification fails to find adequate written description of any molecular probe and binding partner that are to be used in the claimed invention.*" (OA at page 8). However, this assertion has been proven to be false since the specification specifically defines "molecular probe" and "binding partner". For example, a molecular probe can be a nucleic acid or peptide nucleic acid probe (c.f. page 7 of the specification). A "binding partner" can be an antibody used in combination with an antigen (c.f. page 10 of the specification). Thus, unlike the situation in the *University of California* decision, the specification specifically describes embodiments of the claim elements in terms of known compositions (i.e. nucleic acid or peptide nucleic acid probes and antibody/antigen interactions). That nucleic acid probes, peptide nucleic acid probes or antibodies can be used for the identification of bacteria is clear from the many references cited in the Information Disclosure Statements submitted in the application file (e.g. **Reference DB** by Wallner et al.). This fact is also supported by statements in the specification, such as those in the "Background" section. Consequently, there is simply no similarity between the facts of the *University of California* decision and disclosure of the present invention. Consequently, the Examiner's use of the *University of California* decision is misleading, the analysis is incomplete and the conclusions erroneous.

In addition to the foregoing, Applicants wish to make of record the very recent decision in *Capon v. Exhhar*, 2005 U.S. App. Lexis 16865 (August 12, 2005). *In Capon*, is was held that there is no requirement that the nucleotide sequences of chimeric genes must be fully presented where the component DNAs are known. Importantly, the Decision in the *Capon* distinguished the *University of California* and *University of Rochester* decisions upon which the Examiner has placed so much reliance in articulating the present rejection. Simply stated, the *Capon* situation is much closer to the present facts than is situation in either of *University of California* or *University of Rochester* since in

the present situation, the claim limitations "molecular probe" and "binding partner" are embodied by compositions known in the art.

(iii) **Summary**

In summary, it is respectfully submitted that the specification complies with the written description requirement and that in any event the Examiner has not provided any facts that demonstrate the contrary. Accordingly, it is respectfully submitted that the present rejection under 35 U.S.C. § 112, first paragraph, written description, should be withdrawn.

2. **Rejection under 35 U.S.C. § 112, enablement requirement**

(a) The Law

"The purpose of the enablement requirement is to ensure that the invention is communicated to the interested public in a meaningful way." M.P.E.P. § 2164 "However, to comply with 35 U.S.C.§ 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim to that effect."" *Id.* "Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention." *Id.*

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." M.P.E.P. § 2164.01 "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." *Id.*

(b) Analysis of The Examiner's Arguments In View Of The Law

(i) **The Examiner's Assertions are Erroneous**

At paragraph 10 of the present Office Action, the Examiner quotes from "*Enzo Biochem Inc. v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135 bridging to 1136" and asserts that the specification fails to enable one of skill in the art to make and/or use the invention but offers no analysis of any facts. Consequently, the significance of this

paragraph of the rejection is not well stated and therefore requires no reply by Applicants.

At paragraph 11 of the Office Action, the Examiner begins by arguing that Applicants don't possess the invention and therefore cannot have enabled the invention. (OA at page 9) As discussed above, this premise of this argument is without merit. Specifically, Applicants' specification demonstrates possession of the invention. It being based upon an incorrect premise, the conclusion of the Examiner's argument cannot be correct.

The Examiner then argues that: "... *the specification does not provide the essential starting materials or reaction conditions that must be employed when practicing the claimed invention.*" (OA at page 9-10) This too is incorrect.

From the discussion set forth above regarding the written description requirement, it is clear that the specification provides an appropriate description of such claim elements as the "molecular probe" and the "binding partner". The Examiner's attention is further directed to Example 1 (beginning at page 35). In this example, it has been demonstrated that a commercially available coded bead comprising a linked Salmonella specific antibody was able to specifically capture the "stained" detectable *S. choleraesuis* wherein the bacteria were stained with fluorescently labeled PNA probes. Accordingly, this Example demonstrates both possession of the invention and disproves the Examiner's contention that no specific starting materials or reaction conditions have been disclosed by Applicants. The factual basis of the asserted rejection having been disproved, the rejection is improper and should be withdrawn.

Regarding the Examiner's reference to "essential conditions", method claims 1, 18 and 35 contain the claim limitations for each method and the Examiner has failed to describe how any of the disclosed limitations are deficient. The Examiner is further directed to pages 16-17 wherein there is a discussion of such topics as: "Hybridization Conditions/Stringency", "Suitable Hybridization Conditions", "Suitable Antibody Binding Conditions" and "Harmonization Of Suitable Hybridization Conditions & Suitable Antibody Binding Conditions". Clearly these discussions are directions for the ordinary practitioner with respect to operating the methods of the invention. The Examiner is reminded that: 1) "The test of enablement is whether one reasonably skilled

in the art could make or use the invention **from the disclosures in the patent** (emphasis added) coupled with information known in the art without undue experimentation." M.P.E.P. § 2164.01 and that: 2) "Detailed procedures for making and using the invention **may not be necessary** (emphasis added) if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention." M.P.E.P. § 2164. "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." *Id.* Since the Examiner has provided no facts to support his conclusions, the Examiner's bald assertion that: "*the specification does not provide the essential starting materials or reaction conditions that must be employed when practicing the claimed invention*" is not well supported.

Certainly the Examiner is not suggesting that the formation of complexes from binding partners such as antibody/antigen, nucleic acid/nucleic acid, nucleic acid/peptide nucleic acid, enzyme/substrate and receptor/ligand were not well understood and often used in the biological and chemical arts at the time of filing of the present application. Evidence that such an assertion is false can be found in various reference articles that have been introduced into the file for this application by way of the Information Disclosure Statements. Accordingly, very little if any specific instructions should be needed to permit the ordinary practitioner to be successful in such activity and any experimentation to optimize reaction conditions would not be undue since the factors that affect such interactions were well known and understood.

In rebuttal to these arguments made in the Applicants' response dated January 6, 2005, the Examiner appears to merely assert that what the art teaches are the opinions of "applicant's representative" (Office Action at page 11-12). The Examiner did not explain how Example 1 of the specification was deficient. Moreover, as previously stated, what a reference teaches is a matter of fact. *In re Bell*, 991 F.2d 781, 784, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993) The Examiner has failed to explain why the various references cited in the Information Disclosure Statements fail to establish sufficient knowledge in the ordinary practitioner to practice the invention as described. Consequently, the Examiner's contrary position is obvious error.

(ii) **The Examiner Misinterprets The Specification**

At paragraph 12-13 of the Office Action, the Examiner takes statements made in the background of the specification out of context and thereby mischaracterizes the nature of that discussion. The relevant paragraph of the background section of the specification reads:

> *"Nucleic acid hybridization is a fundamental process in molecular biology. Probe-based assays are useful in the detection, quantitation and/or analysis of nucleic acids. Nucleic acid probes have long been used to analyze samples for the presence of nucleic acid from bacteria, fungi, virus or other organisms and are also useful in examining genetically-based disease states or clinical conditions of interest. Nonetheless, nucleic acid probe-based assays have been slow to achieve commercial success. This lack of commercial success is, at least partially, the result of* ***difficulties associated with specificity, sensitivity and/or reliability.***" (bold text quoted by the Examiner)

This quoted paragraph affirmatively states that nucleic acid hybridization is recognized as a fundamental process in molecular biology and that it has long been applied but that it possesses certain deficiencies that make it less than ideal for some commercial applications. Applicant's statement does not lead to the conclusion that nucleic acid hybridization is: *"wrought with "difficulties associated with specificity, sensitivity, and/or reliability"* in a general sense. It merely indicates that there is room for improvement that could lead to more specific, sensitive and reliable assays. That nucleic acid probes can be used for the identification of bacteria is evident from the various references submitted in the Information Disclosure Statements in the application file and is specifically supported by the text quoted above from Applicants' specification. Moreover, the examiner is reminded that: *"...to comply with 35 U.S.C.§ 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim to that effect.""* M.P.E.P. § 2164. Consequently, that nucleic acid probes can sometime exhibit certain difficulties associated with specificity, sensitivity and/or reliability" that might preclude their use in commercial products does not preclude their use in the present invention. For the Examiner to suggest otherwise is inconsistent with the law and with common sense.

In the final sentence of paragraph 12 of the Office Action the Examiner states: *"Even if the claims were to be limited to PNA probes, the specification does not teach which probes are to be used, much less which probes are to be used in combination with various*

molecular probes so that every "species, taxon, subclass, subspecies, serotype, or strain" of the organisms can be identified." It seems that by this statement, the Examiner expects Applicants to list every probe sequence that could ever be used to determine each specific organism to be determined. It suffices to say that no such requirement exists under the law. This is clear because, *"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."* M.P.E.P. § 2164.01 For example, as stated in the background:

> *"Nucleic acid hybridization is a fundamental process in molecular biology. Probe-based assays are useful in the detection, quantitation and/or analysis of nucleic acids. Nucleic acid probes have long been used to analyze samples for the presence of nucleic acid from bacteria, fungi, virus or other organisms and are also useful in examining genetically-based disease states or clinical conditions of interest."*

Since the Examiner has not contested the accuracy of this statement, it is clear that the production of suitable probes is well understood and need not be specifically described in the specification. Moreover, "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." M.P.E.P. § 2164.01 Accordingly, there is simply no requirement under 35 U.S.C. 112, first paragraph that every conceivable sequence and related organism be expressly stated in the specification since the preparation of the requisite probes and binding partners is well understood and practiced. Furthermore, the Examiner has provided absolutely no evidence to the contrary.

In summary, the premises of the Examiner's arguments being incorrect and unsupported by established fact, it is respectfully submitted that the rejection for lack of enablement under 35 U.S.C. § 112, first paragraph should properly be withdrawn.

VII. SUMMARY

It is believed that this response addresses all rejections set forth in the present Office Action and the application is in ready condition for allowance. In consideration of the preceding remarks, Applicants hereby respectfully request reconsideration of all

pending claims, the withdrawal of all rejections set forth in the present Office Action and the issue of a Notice of Allowance by The Office.

VIII. INTERVIEW

If the Examiner believes a telephonic or personal interview would advance the prosecution of the subject application, the Examiner is invited to contact attorney Gildea during business hours at the telephone or facsimile numbers listed below.

IX. FEES

The petition under 37 C.F.R. §1.136(a) that accompanies this paper includes an authorization to deduct the appropriate fee for a two-month extension from Deposit Account 01-2213. No additional fees are believed due The Office for consideration of this paper. If however, The Office determines that any other fee is due, authorization is hereby granted to charge any required fee associated with the filing or proper consideration of this paper to Deposit Account 01-2213.

X. CORRESPONDENCE/CUSTOMER NUMBER

Please send all correspondence pertaining to this document to:

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IF NOT ALREADY DONE, PLEASE MATCH THIS CASE WITH CUSTOMER NUMBER

23544

Respectfully submitted
on behalf of Applicants,

Sept 20, 2005
Date

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